IN THE UNITED STATES PATENT AND TRADEMARK OFFICE


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| IN RE APPLICANT | : Jackowski *et al.* |
| INVENTION | : **Biopolymer Marker Indicative Of Disease State Having A Molecular Weight Of 1562 Daltons** |
| SERIAL NUMBER | : 09/845,738 |
| FILING DATE | : April 30, 2001 |
| EXAMINER | : Cook, Lisa V. |
| GROUP ART UNIT | : 1641 |
| OUR FILE NO. | : 2132.040 |

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CERTIFICATE UNDER 37 CFR 1.8(a)
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 on _____

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 CFR § 1.132**

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled **"Biopolymer Marker Indicative of Disease State Having A Molecular Weight of 1562 Daltons"**, having U.S. Application Serial No. 09/845,738, filed April 30, 2001.

2. In the Office Action mailed on September 9, 2003, claims 3-9, 18-28, and 33-35(as originally presented) were rejected under 35 U.S.C. 112, first paragraph because the claimed invention

allegedly contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims, as amended, have been limited to a specific biopolymer marker peptide consisting of SEQ ID NO:1 (the 1562 dalton marker)which is useful in methods and kits for diagnosing myocardial infarction. The method of the invention as recited in claim 36 involves a comparison of the mass spectrum profile of a peptide consisting of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from a patient sample by carrying out the methods disclosed in the instant specification, wherein recognition of a mass spectrum profile in the patient sample displaying the characteristic profile (a peak at about 1562 daltons) of the mass spectrum of the peptide consisting of SEQ ID NO:1 is indicative of a link to myocardial infarction. In other words, the mass spectrometric profile of the 1562 dalton marker established by the described methods is intended to be used as a reference against which to compare mass spectrometric profiles obtained from unknown samples.

3. In order to provide data which would further support the linkage of the claimed biopolymer marker (SEQ ID NO:1) to myocardial infarction, I contacted Dr. John Marshall, one of the inventors of the instant invention, and asked to be provided with evidence of the absence of the 1562 dalton marker in normal human sera (obtained from patients determined to be healthy with regard to myocardial infarction).

4. The attached figure shows side-by-side (for easy comparison) mass spectrometric profiles; the upper profile obtained from the sera of a patient having myocardial infarction (MI) and the lower profile obtained from the sera (NHS, normal human sera) of a patient determined to be in a normal physiological state with regard to myocardial infarction. This profile comparison clearly evidences the presence of the 1562 dalton marker (SEQ ID NO:1) in myocardial infarction and the absence of such marker in a normal physiological state. Thus, the biopolymer marker of SEQ ID NO:1 is determined to be linked and/or associated with myocardial infarction.

The mass spectrometric profiles shown in the attached figure do not represent new experimentation; they are duplicates of the original profiles established at the time that the experiments described in the specification were first carried out.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

9/30/2005
Date

Ferris H. Lander
Reg. No. 43,377

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